This Program Announcement expires on July 31, 2004, unless reissued.

THE MANAGEMENT OF CHRONIC PAIN

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National Institute of Nursing Research (NINR)
National Institute on Aging (NIA)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
National Center for Complementary and Alternative Medicine (NCCAM)
National Cancer Institute (NCI)
National Institute of Child Health and Human Development (NICHD)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute on Drug Abuse (NIDA)
National Institute of Neurological Disorders and Stroke (NINDS)

THIS PA USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS PA.

PURPOSE

The National Institute of Nursing Research and co-sponsoring Institutes and Centers encourage research proposals in the management of chronic pain across the lifespan. Pain is a subjective experience influenced by gender, age, race/ethnicity and psychosocial factors. The management of pain is influenced by patient, health care provider and system factors. Research is needed to determine the most effective interventions to remove barriers to effective treatment, to determine the most effective pharmacological and non-pharmacological therapies including complementary and alternative therapies, to identify assessment tools for patients unable to verbalize their pain, and to identify effective pain management strategies for individuals with disabilities and underserved populations.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS led national activity for setting priority areas. This Program Announcement (PA), The Management of Chronic Pain, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT

This PA will use the National Institutes of Health (NIH) Research Project Grant (R01) award mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for an application submitted in response to this PA may not exceed 5 years.

Specific application instructions have been modified to reflect "MODULAR GRANT" and "JUST-IN-TIME" streamlining efforts being examined by the NIH. Complete and detailed instructions and information on Modular Grant applications can be found at http://grants.nih.gov/grants/funding/modular/modular.htm

RESEARCH OBJECTIVES

There are more than 50 million Americans who experience chronic pain and more than half of dying patients experience moderate to severe pain during the last days of their life. Pain is a frequent cause for clinical visits with approximately 45% of the population seeking medical help for pain at some point in their lives. Pain is found across the lifespan and it has been estimated that four out of every ten people with moderate or severe pain do not get adequate relief.

Pain is personal and subjective, is affected by mood and psychosocial factors, and demonstrates tremendous individual variation. Depression commonly complicates pain and adds to the disability and impairment found in disorders with chronic pain. Pain in combination with

depression is a risk factor for suicide. Pain interferes with quality of life, sleep and productivity, and pain increases utilization of health care resources. However, many health care providers do not have the background to effectively treat pain.

Pain is frequently undertreated by healthcare providers. For example, a survey of several hundred ambulatory AIDS patients found that fewer than 8% of patients reporting "severe" pain were prescribed a strong opioid such as morphine, despite published guidelines. Adjuvant analgesic drugs (e.g., antidepressants) were also prescribed to only a small fraction of these patients. Opioid analgesics are the accepted treatment for acute pain, cancer pain and pain at the end of life, and recently have been recommended for chronic, nonmalignant pain. Patients can be treated with this therapy without developing tolerance, addiction or toxicity. Nevertheless, health care providers continue to fear these adverse outcomes, and believe that opioid use may result in a downhill spiral of further disability, depression and pain, in spite of contrary evidence. A further barrier to chronic opioid therapy is the lack of a good objective measure to determine whether a person requesting increased opioid dosage is abusing opioids or is receiving insufficient benefit from therapy. This second scenario is so common in certain conditions (e.g., cancer, sickle cell disease) that the term “pseudo addiction,” has been used to describe the patient who is demonstrating drug-seeking behavior because his or her pain is undertreated.

In addition to health care provider barriers, there are patient and family barriers to effective pain relief. Patients may underuse effective pharmacological treatments because of a stoic or fatalistic attitude, and/or a belief that complaining of pain makes one a “bad” patient. Patients with cancer may believe that cancer pain cannot be alleviated; they may fear that pain indicates disease progression and/or they may fear that current usage will lead to future ineffectiveness. Patients who are treated with opioids may have additional fears of dependence, addiction and tolerance, and fear of injections. Thus, underusage may also be due to the stigma of using opioids. Research is needed to determine the relationship between patient-related barriers and pain management and to determine whether the patient barriers are a cause or result of inadequate treatment.

Pain and pain management in infants is another area of research need. Premature infants often undergo painful medical and surgical procedures and may be in ongoing pain as a result. Until recently it was believed that infants are insensitive to pain because of their immature nervous systems. Recent research demonstrates that infants do feel pain and a recent study on an animal model demonstrated that the pain experienced as a neonate resulted in greater sensitivity to pain as an adult. Thus, painful procedures in infancy may lead to permanent

changes in the pain threshold. Effective pain interventions are needed for premature infants who are now surviving due to medical and technical advances.

Individuals with certain demographic characteristics or medical conditions are likely to experience less effective pain management and report higher pain levels than others. Older patients are often undertreated, especially the cognitively impaired. Women may experience further undertreatment as they are over represented in certain conditions associated with pain such as fibromyalgia and temporomandibular joint disorders. In addition, individuals with less education or lower incomes, minority patients, patients with a history of injection drug use, and patients with AIDS are at risk for receiving suboptimal pain treatment. The specific barriers to the undertreatment and underuseage of pain medication and non-pharmacological regimens need to be identified in these underserved populations.

Similarly, chronic pain is frequently undertreated in those who are unable to verbalize their pain (e.g., premature infants, cognitively impaired individuals). Assessment of chronic pain in nonverbal populations is difficult. Sympathetic arousal is frequently found in acute pain, but is not commonly found in patients with chronic pain and therefore a patient may not look as if s/he is in pain. The cues suggesting pain in nonverbal patients can be identified by those who are familiar with the patient and who can detect changes in behavior. However, in any health care facility and particularly the long-term care facility, the staff turnover and different patient assignments are barriers to the assessment of pain in nonverbal patients. Some cognitively impaired elders can report pain reliably in response to simple questions. However, pain needs to be assessed in order to be treated. The Department of Veterans Affairs and other health care institutions have institutionalized the assessment of pain as a fifth vital sign, similar to other vital signs like blood pressure, pulse, temperature and respiratory rate. Other innovative systematic approaches to pain management are needed. Educational training is not sufficient for instituting changes in pain management; further research on other institutional changes is needed to support pain management interventions in the practice setting.

Non-pharmacological treatments have been found to be effective in managing chronic pain either alone or in combination with pharmacological therapy. These treatments include relaxation training, cognitive behavioral interventions, family support, biofeedback, and improving self-efficacy. Further research is needed to refine the most effective treatment strategies for specific conditions and to determine the most effective treatment strategies for underserved populations. This research should include investigation of innovative complementary and alternative therapies for the effective treatment of chronic pain such as acupuncture, spinal manipulation and botanical products. A recent report concluded that there is little research on the management of cancer

pain. The report recommended that further research is needed to determine the best combinations of pharmacological and non-pharmacological regimens in long-term cancer patients and in children with cancer pain. In addition, further research is needed to determine the impact of ethnicity, race, gender, age, psychosocial context and culture on cancer pain.

Listed below are examples of studies that would be responsive to this program announcement. However, these are only illustrative examples and applicants are encouraged to propose other topics consistent with the goals of this program.

o Test interventions to remove the barriers to the effective treatment of pain by health care providers for all patients including those who are underserved;

o Test interventions to remove the barriers to the usage of pharmacological therapy by patients;

o Determine factors associated with the under-reporting of chronic pain and/or reporting that a treatment is effective when pain is not relieved;

o Develop and test measurement tools to assess chronic pain in patients who are unable to verbalize their pain (e.g., infants, patients with dementia);

o Further explore the relationship between painful procedures and future pain sensitivity in premature infants;

o Identify innovative biobehavioral interventions to control and alleviate chronic pain and the associated psychological distress in clinical and home settings;

o Identify and test complementary and alternative therapies either alone or in combination with conventional therapies for the control and alleviation of chronic pain;

o Test innovative methods for translating scientific advances in pain management into practice settings;

o Identify which of the patient barriers are a cause or a result of psychological distress;

o Develop a clinically effective monitoring system for opioid adherence and objective measures of tolerance and addiction;

o Identify the patient and/or health care provider barriers associated with the underusage or undertreatment of pain specific for different cultural and ethnic/minority populations;

o Test non-pharmacological interventions separately and in combination with pharmacological interventions to determine the most effective chronic pain management regimen;

o Determine whether sensitivity or reactivity to pain is affected by dementia in the elderly;

o Investigate the consequences of pharmacological pain management on cognition and functional abilities in the elderly, and particularly in persons with dementia;

o Use psychophysical techniques to investigate pain threshold changes throughout the lifespan in patients experiencing chronic pain;

o Study nociceptive pathways in older people with and without chronic pain using neuroimaging methods;

o Study assessment and treatment of chronic pain in drug abusing populations both in and out of drug abuse treatment and study the effects of under-, over-, and appropriate treatment of chronic pain on the development and relapse of drug abuse;

o Study interactions among drugs of abuse, medications used to treat drug abuse and its co-morbid conditions and medications used to treat drug abuse; and

o Assess the medical/health consequences of abused/over-used pain medications.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm: The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

All investigators proposing research involving human subjects should read the policy that was published in the NIH Guide for Grants an Contracts, June 5, 2000 (Revised August 25, 2000), available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at:http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 4/98) and will be accepted at the standard application deadlines as indicated in the application kit. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: GrantsInfo@nih.gov.

Applicants planning to submit an investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended/revised version of the preceding grant application types requesting $500,000 or more in direct costs for any year are advised that he or she must contact the Institute or Center (IC) program staff before submitting the application, i.e, as plans

for the study are being developed. Furthermore, the application must obtain agreement from the IC staff that the IC will accept the application for consideration for award. Finally, the applicant must identify, in a cover letter sent with the application, the staff member and Institute or Center who agreed to accept assignment of the application.

This policy requires an applicant to obtain agreement for acceptance of both any such application and any such subsequent amendment. Refer to the NIH Guide for Grants and Contracts, March 20, 1998 at http://grants.nih.gov/grants/guide/notice-files/not98-030.html

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and Institute staff. The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants, with the modifications noted below.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS
BUDGET INSTRUCTIONS

Modular Grant applications will request direct costs in $25,000 modules, up to a total direct cost request of $250,000 per year. (Applications that request more than $250,000 direct costs in any year must follow the traditional PHS 398 application instructions.) The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

PHS 398

o FACE PAGE: Items 7a and 7b should be completed, indicating Direct Costs (in $25,000 increments up to a maximum of $250,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See http://grants.nih.gov/grants/funding/modular/modular.htm for sample pages.) At the top of the page, enter the total direct costs requested for each year. This is not a Form page.

o Under Personnel, list all project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided. However, the applicant should use the NIH appropriation language salary cap and the NIH policy for graduate student ompensation in developing the budget request.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest $1,000. List the ndividuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of all personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the Letter of Intent to establish a consortium.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at: http://grants.nih.gov/grants/funding/modular/modular.htm

- Complete the educational block at the top of the form page;
- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years.
- List selected peer-reviewed publications, with full citations;

o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

The title and number of the program announcement must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and five signed photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be evaluated for scientific and technical merit by an appropriate scientific review group convened in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these

criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

o The reasonableness of the proposed budget and duration in relation to the proposed research

o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

AWARD CRITERIA

Applications will compete for available funds with all other recommended applications. The following will be considered in making funding decisions: Quality of the proposed project as determined by peer review, availability of funds, and program priority.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.361 (NINR), 93.866 (NIA), 93.846 (NIAMS), 93.213 (NCCAM), 93.393 (NCI), 93.929 (NICHD), 93.158 (NIDCR), 93.279 (NIDA), and 93.853 (NINDS). Awards are made under authorization of sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Return to Volume Index
Return to NIH Guide Main Index